

Reconsideration of the above-identified application is respectfully requested in view of the following amendments and remarks.

### **REMARKS**

#### ***Status of the Claims***

Claims 1-16 and 30-32 are pending. Claims 1-16 and 30-32 have been rejected.

#### ***Rejections under 35 U.S.C. § 103***

The Examiner has rejected claims 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Youssefych et al. (U.S. Pat. No. 5,968,519) in view of Lee (U.S. Pat. No. 5,552,162). Applicant respectfully traverses this rejection.

According to the Examiner, Youssefych et al. ('519) teaches a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury with a composition of finely divided powder of safflower seed or its extract contained in a pharmaceutically acceptable carrier." See Office Action at page 3, last paragraph. The Examiner further states that Youssefych et al. teaches the use of topical formulations containing corticosteroids and a film-forming material, such as cellulose derivatives.

The Examiner further contends, Lee teaches a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a

therapeutically effective amount of medicament.” See Office Action at page 5-6. The Examiner then concludes “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefeyeh.” See Office Action at page 6, third paragraph. Applicant respectfully disagrees with this conclusion.

As the Examiner points out, Youssefeyeh et al. is directed to the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury. By contrast, the presently claimed invention is directed to, “[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises; applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.” See claim 1, as presently pending (emphasis added). This method is not taught or suggested by Youssefeyeh et al.

Applicant respectfully points out that Youssefeyeh et al. does not disclose or suggest a method for treating healed wounds so as to reduce scarring and/or improve the appearance of scars. In fact, the Examiner points this out stating that Youssefeyeh “does not explicitly teach treatment of ‘healed wounds.’” See Office Action at page 5, third paragraph. Nevertheless, according to the Examiner, Youssefeyeh et al. “teaches methods of treatment and conditions to be treated as taught by Youssefeyeh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof.” See Office Action at page 5, third paragraph. Applicant respectfully disagrees.

Applicant respectfully asserts that the treatment of inflammation and pain associated with inflammatory dermatoses, gingivitis and acute injury, as taught and disclosed in Youssefych et al., is not the same as treating healed wounds so as to reduce scarring and/or improve the appearance of scars, as presently claimed. Rather, the methods taught by the present invention and those taught by Youssefych et al. are directed to treating completely different conditions. Again, the former discloses a method to reduce scarring and/or improve the appearance of scars and the later teaches a method of treatment for inflammation and pain associated with inflammatory dermatoses. Scarring is not a form of inflammatory dermatoses. Furthermore, Applicant respectfully asserts that the teaching of a method to treat an inflammatory dermal condition does not in any way suggest treating healed wounds to reduce scarring or improve the appearance of scars. As such, prior to Applicant's invention there was no reason or suggestion to use the composition taught in Youssefych et al. to treat healed wounds to reduce scarring or improve the appearance of scars. There is simply no suggestion whatsoever, that the compositions disclosed in Youssefych et al. can be used for "treating healed wounds so as to reduce scarring and/or improve the appearance of scars," as presently claimed.

The Examiner cites Lee to overcome the deficiencies of Youssefych et al. More specifically, as the Examiner correctly points out, Lee is directed to a method for improving the size and appearance of scar tissue. According to Lee, the method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. Lee also discloses the use of a therapeutically effective medicament with the thermal insulating material. Again, see Lee in the Abstract.

However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening that carrier into a tangible membrane juxtaposed to the healed wound in method for treating healed wounds to reduce scarring or improve the appearance of scars, as presently claimed. Moreover, Applicant respectfully asserts that prior to Applicant's invention the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known.

The Examiner is also correct in pointing out that methods were known prior to Applicant's invention for the improving the size and appearance of scar tissue. In fact, Applicant has pointed out many such known methods in the Background section of the present application. According to Applicant's specification, "[t]he use of pressure dressings is believed to be the first truly effective scar treatment...[h]owever, pressure dressings are bulky rendering them uncomfortable to the user and often inconvenient to keep in place on the affected scar tissue." See Applicant's specification at page 4, lines 3-11. Applicant further pointed out that "[i]n less severe cases, cortisone creams or cortisone tapes do show modest benefit... [h]owever, creams are often inconvenient to use as they are messy and can stick to and discolor clothing. The use of tapes are also disadvantageous as such tapes often hold moisture and fall off the affected area." See Applicant's specification at page 4, lines 12-22. However, the use of a film-forming carrier to treat healed wounds to reduce scarring or improve the appearance of scars was not known prior to Applicant's invention. As Applicant points out, "while there have been physical treatments, compositions and/or articles which contain medicaments which have had modest success in reducing, softening and lightening hypertrophic scars, these prior attempts are expensive, inconvenient to use, difficult to apply or simply have not been very effective in achieving the desired purpose." See Applicant's specification at page 7, lines 11-16.

Whereas the film-forming composition of the present invention “can be applied directly onto the healed wound or formed scar to be treated without the need for rubbing of the application of pressure such as with oily or greasy carriers which application can often be painful to the person whose wound or scar is being treated.” See Applicant’s specification at page 9, lines 11-15.

Furthermore, Applicant respectfully asserts that one of skill in the art would not look to the composition disclosed in Youssefeyeh et al. to treat scar tissue. Again, there is simply no indication whatsoever in Youssefeyeh et al. that the composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of scars. Furthermore, Applicant respectfully asserts that one of skill in the art would not look to Youssefeyeh et al. to improve the formulation disclosed in Lee for treating scars. There is simply no reason to combine elements of the composition disclosed in Youssefeyeh et al., which teaches a composition for treatment of inflammation and pain, with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. Applicant respectfully points out that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some reason to do so.

Moreover, it is Applicant’s position that one of skill in the art, without the benefit of Applicant’s disclosure, would not be capable of arriving at the presently claimed invention. Applicants respectfully assert that the Examiner is relying on Applicants’ claim and/or disclosure to piece together elements to provide an argument for obviousness. Such piece-mealing together of elements is not permitted. Moreover, without looking to Applicant’s specification there is simply no reason to combine the specific elements claimed (a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane

juxtaposed to the healed wound and using that composition to treat healed wounds to reduce scarring or improve the appearance of scars), from among the disclosures of Youssefeyeh et al. and Lee to come up with the presently claimed film. There is simply no suggestion whatsoever of the presently claimed combination in Youssefeyeh et al. or Lee.

As such, Applicant respectfully asserts that the combination of Youssefeyeh et al. with Lee does not and cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner has rejected claim 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162). Applicant respectfully traverses this rejection.

According to the Examiner, “Mantelle (‘070) teaches flexible, finite, bioadhesives compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents.” See Office Action at pages 6-7. The Examiner continues, “[w]hile the prior art does not explicitly teach treatment of ‘healed wounds’, the prior art nonetheless explicitly teaches compositions that are topically applied on the skin for the effective treatment of pain. The method comprises applying a therapeutically effective amount of a pharmaceutical agent, a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent in the carrier. The compositions are suitable for topical application on the skin.” See Office Action at page 7, sixth paragraph.

According to the Examiner, Lee teaches a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound

healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament.” See Office Action at pages 7-8. The Examiner concludes, “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, particularly hypertrophic scars such as taught by Lee within the methods of Mantelle.” See Office Action at page 8, third paragraph. Applicant respectfully disagrees with this conclusion.

As previously mentioned, the presently claimed invention is directed to, “[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises; applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.” See claim 1, as presently pending (emphasis added). This method is not taught or suggested by Mantelle. Rather, as the Examiner points out, Mantelle is directed to a flexible, finite, bioadhesives compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents. Applicant respectfully points out that Mantelle does not teach or suggest a method to treat healed wounds to reduce scarring or improve the appearance of scars. The Examiner has acknowledged this fact. See Office Action at page 7, second to last paragraph.

The Examiner cites Lee to overcome the deficiencies of Mantelle. More specifically, as the Examiner correctly points out, Lee is directed to a method for improving the size and appearance of scar tissue. According to Lee, the method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. Lee also discloses the use of a therapeutically effective medicament with the thermal insulating material. Again, see Lee in the Abstract. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening that carrier into a tangible membrane juxtaposed to the healed wound in method for treating healed wounds to reduce scarring or improve the appearance of scars, as presently claimed. Moreover, Applicant respectfully asserts that prior to Applicant's invention the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known.

Furthermore, Applicant respectfully asserts that one of skill in the art would not look to the composition disclosed in Mantelle to treat scar tissue. Again, there is simply no indication whatsoever in Mantelle that the composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of scars. Furthermore, Applicant respectfully asserts that one of skill in the art would not look to Mantelle to improve the formulation disclosed in Lee for treating scars. There is simply no reason to combine elements of the composition disclosed in Mantelle with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. Applicant respectfully points out that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some reason to do so.



Moreover, it is Applicant's position that one of skill in the art, without the benefit of Applicant's disclosure, would not be capable of arriving at the presently claimed invention. Applicants respectfully assert that the Examiner is relying on Applicants' claim and/or disclosure to piece together elements to provide an argument for obviousness. Such piece-mealing together of elements is not permitted. Moreover, without looking to Applicant's specification there is simply no reason to combine the specific elements claimed (a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound and using that composition to treat healed wounds to reduce scarring or improve the appearance of scars), from among the disclosures of Mantelle and Lee to come up with the presently claimed film. There is simply no suggestion whatsoever of the presently claimed combination in Mantelle or Lee.

As such, Applicant respectfully asserts that the combination of Mantelle with Lee does not and cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

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Respectfully submitted,



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